

Guidelines for the use of Rh (D) immunoglobulin

in pregnant women with Rh (D) negative blood group, and no pre-existing anti-D antibodies

Date effective: by 31 March 2006

For each sensitising event*, administer Rh (D) immunoglobulin as indicated below.

Week 1 to Week 12
(first trimester)

Beyond Week 12
(second & third trimester)

Postpartum

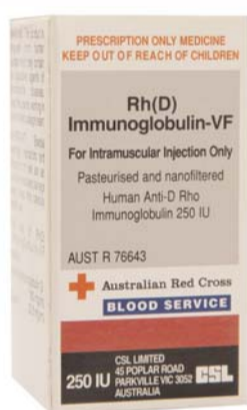
Rh (D) Immunoglobulin-VF
(Single pregnancy)

Rh (D) Immunoglobulin-VF
(Multiple pregnancy#)

Rh (D) Immunoglobulin-VF

Rh (D) Immunoglobulin-VF

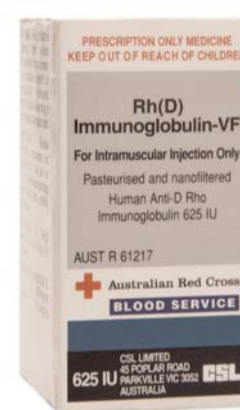
250 IU
Solution for
intramuscular
injection



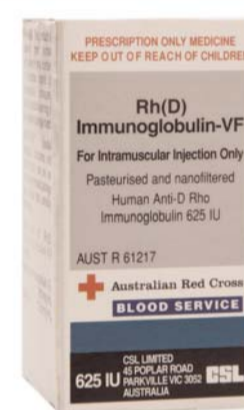
625 IU
Solution for
intramuscular
injection



625 IU
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intramuscular
injection



625 IU
Solution for
intramuscular
injection



Routine prophylaxis is recommended for ALL Rh (D) negative pregnant women (Primigravida/Multigravida).

***Sensitising events include:**

normal delivery, ectopic pregnancy, miscarriage, termination of pregnancy and ultrasound needle guided procedures such as chorionic villus sampling, amniocentesis, cordocentesis and fetoscopy. Also abdominal trauma considered sufficient to cause fetomaternal haemorrhage, external cephalic version or antepartum haemorrhage.

Multiple pregnancy refers to more than one fetus in utero, for example twins or triplets.

References

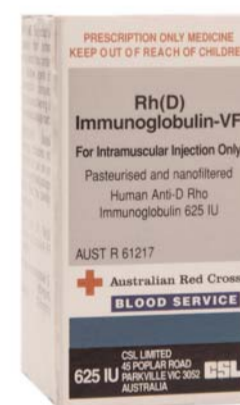
1. National Blood Authority Guidelines on the prophylactic use of Rh (D) immunoglobulin (anti-D) in obstetrics, June 2003.

Administer at Week 28 and Week 34

Rh (D) Immunoglobulin-VF

625 IU

The doses at 28 & 34 weeks
are given in **ADDITION**
to any doses given
for sensitising events.



Original studies¹ have shown that 100 IU of Rh (D) immunoglobulin is sufficient to protect against a Fetomaternal Haemorrhage (FMH) of 1.0 mL of fetal red cells (2 mL whole blood).

For example, Rh (D) immunoglobulin 625 IU is sufficient to protect against a Fetomaternal Hemorrhage (FMH) of 6.0 mL of fetal red cells (12 mL of whole blood).

In some circumstances, access to an intravenous Rh (D) immunoglobulin preparation may be warranted. A quantity of intravenous Rh (D) immunoglobulin will be available for this purpose. Contact ARCBS for further information.

The batch number of every vial of human immunoglobulin administered must be recorded in the patient's medical history and in accordance with other legal statutory requirements.

Please review the approved Product Information before prescribing. **Refer to boxed warning in Product Information.** **INDICATIONS:** The prevention of Rh sensitisation in Rh (D) negative females at or below child bearing age. **CONTRAINDICATIONS:** Individuals who are Rh (D) positive or D^u positive; Rh negative and D^u negative individuals previously sensitised to the Rh (D) antigen; individuals with IgA deficiency; individuals with coagulation disorders that would contraindicate intramuscular injections. **SPECIAL WARNINGS:** Rh (D) Immunoglobulin-VF is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jacob Disease (CJD) agents, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors, and by dedicated virus removal and inactivation procedures included in the manufacturing process. Despite these measures, such products may still potentially transmit disease. Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate. **PRECAUTIONS:** Rh (D) Immunoglobulin-VF must not be administered intravenously. It should not be given to Rh (D) positive infants. Rh (D) Immunoglobulin-VF should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Rh (D) Immunoglobulin-VF may interfere with subsequent serological testing. It may affect responses to live attenuated viral vaccines. **ADVERSE EFFECTS:** Local tenderness, erythema and stiffness at the injection site. For less common reactions consult approved Product Information. **DOSAGE & ADMINISTRATION:** 250 IU after sensitising events during the first trimester of pregnancy; this should be increased to 625 IU for twin and multiple pregnancies. 625 IU after sensitising events beyond the first trimester. For mismatched transfusions or large foetomaternal bleeds 100 IU Rh (D) Immunoglobulin-VF should be administered for each 1.0 mL of Rh (D) positive red cells. The dose should be given as early as possible and within 72 hours of exposure. Rh (D) Immunoglobulin-VF should be given by intramuscular injection and does not contain an antimicrobial agent. The approved Product Information is available from CSL Limited, Bioplasma Division, 189-209 Camp Road Broadmeadows VIC 3047 Australia (ABN 99 051 588 348). For Medical/Technical Inquiries: (Toll free) 1800 067 140.

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